IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

DANIEL HUBERT, individually and on behalf of all others similarly situated, Plaintiff, v. GENERAL NUTRITION CORPORATION, Defendant. (In re: GNC Picamilon/BMPEA Litigation)	:	Civil Action No. 2:15-cv-01391-MRH Oral Argument Requested This Document Relates to: All Actions

DEFENDANT GENERAL NUTRITION CORPORATION'S BRIEF IN SUPPORT OF MOTION TO DISMISS FIRST AMENDED CONSOLIDATED COMPLAINT

Defendant General Nutrition Corporation ("GNC"), by and through its attorneys Amy B. Alderfer, Esquire, Paul K. Leary, Jr., Esquire, and Brett N. Taylor, Esquire, and the law firm Cozen O'Connor, file the following Brief in Support of GNC's Motion to Dismiss Plaintiffs' First Amended Consolidated Class Action Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) and (6), for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

MEMORANDUM

I. INTRODUCTION

This matter is a virtual copy-cat lawsuit stemming from a misguided and meritless action that was filed in Oregon by the Attorney General for the State of Oregon ("OAG")[1] because GNC would not pay the OAG an unwarranted seven-figure penalty it demanded. The OAG action like the ones *sub judice*, are based on the false premise that BMPEA, picamilon and now *Acacia rigidula*, have been adjudicated to be "illegal" ingredients. They have not! The OAG action and putative class plaintiffs here all contend that GNC sold "illegal" ingredients in violation of myriad state unfair trade practices laws. All they have to rely on are Food and Drug Administration "FDA" warning letters that only threaten enforcement actions (if products are not voluntary removal from market) and a declaration of an FDA official that opines that picamilon is "illegal" and which was produced primarily to support the OAG action. It necessarily follows that if these Plaintiffs cannot prove that BMPEA, picamilon and *Acacia rigidula* are "illegal," these cases must be dismissed.

Plaintiffs' recently amended Complaint adds only additional similar allegations regarding *Acacia rigidula*, and does nothing to cure the fatal flaws of the Original Complaint. Notwithstanding that, following the filing of the OAG Action, in which GNC is continuing to defend itself, Plaintiffs cherry-picked allegations from the OAG's complaint and then filed five lawsuits, now consolidated, with claims alleging that GNC violated the law by selling dietary supplements containing two "illegal" ingredients— picamilon and BMPEA. It is clear that the OAG and Plaintiffs failed to investigate the FDA's positions regarding these ingredients and the

[1] References to "OAG Action" herein refer to the Oregon litigation, United States District Court for the District of Oregon, Case number 3:15-cv-02006-PK. References to "OAG" refer to Mr. David Hart, Assistant Attorney in Charge for the Health Fraud Unit/Consumer Protection Section at the Oregon Department of Justice. The Attorney General of Oregon is Ellen Rosenblum.

timing of GNC's removal of such products containing them prior to suing GNC. Indeed, Plaintiffs (and the OAG) now seek to impose damages and penalties upon GNC for selling products containing BMPEA, picamilon, and/or *Acacia rigidula* despite the fact that, to this very day, there has been no final agency action or enforcement action declaring these ingredients unlawful, and it is beyond dispute that GNC began removing all such products well in advance of even any warnings from the FDA.

Although Plaintiffs' allegations and claims regarding picamilon and BMPEA are cribbed wholesale from the meritless OAG Action, their claims in this case must be dismissed regardless of the outcome of the OAG Action for at least four reasons. First, the Plaintiffs lack standing because they have failed to plead an injury stemming from the products at issue. Indeed, GNC started removing BMPEA a full 12 days before any FDA warning letters were sent to others. Picamilon was removed by GNC more than 60 days before any FDA warning letter. Regarding *Acacia rigidula*, the FDA did not take any action whatsoever regarding it until March 2016, almost a year after GNC had removed products containing *Acacia rigidula* from its selves. To be clear, GNC voluntarily took immediate steps to remove these ingredients from its shelves as soon as questions began to surface about the legal status of BMPEA, picamilon and *Acacia rigidula* as dietary ingredients. Second, each of the Plaintiffs' claims is preempted by federal law. Congress vested authority to enforce the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq,* exclusively in the federal Food & Drug Administration ("FDA"). A review of the Complaint makes clear that Plaintiffs are attempting to enforce this same statute, through this private litigation, but their claims would not exist were it not for the FDCA so they are preempted.[2] Third, there has been no enforcement action by the FDA regarding picamilon,

[2] Plaintiffs make this clear in paragraph 2 of the Complaint, in which they allege that GNC "repeatedly violated federal and state law by selling supplements with mislabeled dietary ingredients which are not even legally available

BMPEA, or *Acacia rigidula*, let alone a final agency action. Instead, as part of a back-door litigation strategy, the OAG procured a declaration from Dr. Cara Welch—the same FDA official who only four short months earlier signed an FDA Certificate of Free Sale for two of the very picamilon-containing products at issue here. Notably, that certificate indicated that those products were freely marketed in the United States. GNC had no opportunity to respond to this declaration through the typical statutory administrative procedures—a violation of GNC's due process rights. The administrative procedures must play out and the FDA must take final agency action before the Plaintiffs can sustain claims against GNC.[3] Fourth, GNC relied upon guarantees from its vendors. Consistent with the FDCA, the vendors warranted that the products sold to GNC were lawful. That reliance is justified under the "FDA Guarantee," discussed below.

II. LEGAL STANDARDS

A. Lack of Subject Matter Jurisdiction Under FRCP 12(b)(1)

Federal Rule of Civil Procedure 12(b)(1) governs a motion to dismiss for lack of standing, since "standing is a jurisdictional matter." *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). Standing is a threshold question of subject matter jurisdiction that must be satisfied before a plaintiff may bring a cause of action in federal court. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992); *Pub. Interest Research Group of N.J. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 117 (3d. Cir. 1997). A court may not create jurisdiction by curing deficient standing allegations. *Whitemore v. Arkansas*, 495 U.S. 149, 155–56 (1990). The plaintiff bears the burden of establishing that jurisdiction exists. *Petruska v. Gannon Univ.*, 462

in prescription drug form in the United States, let alone as a supplement to the diet." Elsewhere in the Complaint Plaintiffs directly reference the FDCA's provisions governing dietary supplements.

[3] We note that industry commentators are also concerned that the FDA has delegated its authority to the states by doing so has violated due process standards by issuing a declaration with no administrative mechanism for GNC to appeal. *See, e.g.*, http://www.usatoday.com/story/news/2015/10/22/oregon-lawsuit-gnc-supplements/74344318/.

F.3d 294, 302, n. 3 (3d Cir.2006).

B. Failure to State a Claim Under FRCP 12(b)(6)

To survive a motion to dismiss for failure to state a claim, a complaint must contain factual allegations sufficient to "raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A plaintiff must plead affirmative factual content that "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949 (2009).

A complaint should be dismissed where "it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Famology.com, Inc. v. Perot Systems Corp.*, 158 F. Supp. 2d 589, 590 (E.D. Pa. 2001) (citing *H.J. Inc. v. Northwestern Bell Tel. Co.*, 492 U.S. 229, 249-50 (1989). Although the court must accept as true the facts alleged in the complaint, the court "need not credit a plaintiff's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss." *Id.* at 591 (citing *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997)).

C. Judicial Notice and Documents Relied Upon by Plaintiffs

Although the purpose of a motion to dismiss is to test the legal sufficiency of a plaintiff's claims, reading allegations in the light most favorable to the plaintiff, the court is not required to reason in a vacuum. *See Wright & Miller, Federal Prac. and Procedure* § 1357, at 376. At any stage of the proceeding, the court may take judicial notice of facts "not subject to reasonable dispute" because such facts are "generally known" or "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Documents under the seal of the Secretary of the Department of Health and Human Services made in connection with the function of the Department "shall be judicially noticed" under the plain language of 42 U.S.C. § 3505. (See Declaration of Steven Cherry

("Cherry Dec.") and Request for Judicial Notice, Ex. D)

On a motion to dismiss, "a court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document…. Moreover, a document that is integral to or explicitly relied upon in the complaint may be considered in a motion to dismiss…." *Karl v. Donaldson, Lufkin & Jenrette Sec. Corp.*, 78 F. Supp. 2d 393, 395 n.4 (E.D. Pa. 1999); *see also Pension Benefit Guar. Corp. v. White Consol. Indus*., 998 F.2d 1192, 1196 (3d Cir. 1993) (were the law otherwise, "a plaintiff with a legally deficient claim could survive a motion to dismiss simply by failing to attach a dispositive document on which it relied").

III. STATEMENT OF FACTS/PROCEDURAL HISTORY

A. Pending Oregon Litigation

This action would not exist were it not for the lawsuit filed by the OAG. On October 22, 2015, the OAG sued GNC in Oregon state court. The OAG's Complaint depends entirely on the predicate allegation that GNC violated the FDCA. (Declaration of Stephen Cherry, Ex. I.) The Complaint is pleaded under a state statute, Oregon's Unlawful Trade Practices Act ("UTPA"). The OAG did not allege, however, that GNC violated some independent provision of state law governing ingredients in dietary supplements. Rather, the OAG alleged that GNC violated the UTPA by selling dietary supplements containing picamilon or BMPEA, which, according to the OAG, were not "lawful dietary ingredients" under the FDCA during the time period when GNC sold such dietary supplements. The central allegation of the Complaint is that by violating the federal FDCA, GNC also violated the UTPA. (*Id*. Pg. 1, lines 15-19) The OAG's Complaint – on which Plaintiffs in these cases rely completely – implausibly alleges that even absent *any* FDA direction suggesting that a commonly sold ingredient is unlawful under the FDCA, a retailer can be held liable under state law for selling third-party products containing an ingredient

that the retailer "*should have known*" was unlawful? In fact, the FDA had never pronounced that either ingredient was unlawful or unsafe prior to 2015 – to the contrary, the FDA's public record was indicative of their legality and safety.

B. The Dr. Cara Welch Declaration and Certificate of Free Sale

A declaration signed by Dr. Cara Welch, PhD is the evidentiary centerpiece for the picamilon portion of the OAG action and the present case. It is the *only* support relied upon to for the legal conclusion that picamilon is not a lawful dietary ingredient. This declaration was solicited in the context of litigation by the OAG as leverage to force a quick payout from GNC. (Cherry Dec. ¶ 8.) To illustrate, in an email the OAG sent to GNC's local counsel in Oregon, Mr. Hart stated that GNC "should be aware of the assistance that FDA is providing in this matter." (*Id.* ¶ 9, Ex. F.) He went on to state that the declaration "will be used in any litigation" and then advised that the OAG's Complaint would seek civil penalties going back to 2007.[4] (*Id.*) In order for GNC to stave off the Oregon litigation, it would have had to pay well in excess of $1,000,000. (*Id.* ¶ 15.)

As illustrated by the OAG's correspondence, Dr. Welch's Declaration was not the result of spontaneous agency action, but rather was drafted at the specific request of the OAG to use as leverage to force GNC's capitulation and for use in planned litigation. Fittingly, the declaration is attached as an exhibit to the OAG's Complaint but the declaration was never provided by the FDA to GNC. (*Id.* ¶ 17.) To this day, GNC has never received Dr. Welch's Declaration or any other picamilon-related formal notice directed to GNC from the FDA. (*Id.*)

Dr. Welch's Declaration is troubling not only because of the context surrounding its

[4] It is ironic in a case where the OAG claims that GNC knew or should have known that picamilon was not a lawful dietary ingredient "since 2007", he was not able to point to any existing FDA action, finding, or document. Astonishingly, the OAG's only recourse was to personally solicit FDA "assistance" through a declaration about an issue FDA had never taken any official negative public position on or even discussed publicly.

creation, but also because it is notably inconsistent with a Certificate of Free Sale signed by Dr. Welch just months earlier. On April 15, 2015, Dr. Welch affixed her signature to a Certificate of Free Sale for two picamilon-containing products, namely, RIPTEK V2 and TESTEK. (*Id*. ¶ 7, Ex. D.)[5] The Certificate bears the office seal of the Department of Health and Human Services.

According to FDA's website, a Certificate of Free Sale indicates that a particular product is marketed in the United States or eligible for export, "and that the particular manufacturer has no unresolved enforcement actions pending before or taken by FDA." These certificates may be issued by FDA or by a State governmental authority.[6] The Certificates in essence announce to the world that the subject products are freely (and lawfully) available for sale in the U.S. And importantly they are relied upon by, among others, GNC vendors and foreign regulatory bodies that are responsible for decisions to approve products for sale in their countries. Thus, as of April 15, 2015, the FDA's public position was that picamilon was (at least impliedly) a lawful dietary ingredient. The Certificate, attached as Exhibit D to the Declaration of Stephen Cherry filed herewith, is a self-authenticating public document and this court should take judicial notice of its existence and content. 12 U.S.C. § 3505; Fed. R. Evid. 201(b); 902(1).

On September 29, 2015, literally within minutes of learning of Dr. Welch's contrary declaration and out of an abundance of caution, GNC immediately removed ALL products containing picamilon from its shelves. (Cherry Dec. ¶ 10.)

Dr. Welch signed her declaration on September 28, 2015. More than 60 days thereafter, the FDA made its first public statement regarding picamilon by issuing warning letters on November 30, 2015, to five manufacturers of products containing picamilon.[7] This conspicuous

[5] These two products are manufactured by QNT International, Inc. and are two of the products included in Plaintiffs' Complaint.
[6] http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm2006911.htm. (Alderfer Dec., Ex. J.)
[7] http://www.fda.gov/food/dietarysupplements/productsingredients/ucm472881.htm. (Alderfer Dec., Ex. K.)

inaction leads to the inescapable conclusion that Dr. Welch's declaration had but one purpose when it was written: to assist the OAG in litigation. Despite Dr. Welch's apparent complete reversal of position on picamilon, it took the FDA more than two months to issue a single warning letter. (Cherry Dec. ¶ 11.) It seems unfathomable that GNC could be a litigation target here when it removed picamilon products months before warning letters! As noted above, GNC has never received any notices from FDA about picamilon (or BMPEA) and by November 30 all picamilon-containing products had been off GNC's shelves for sixty days for more. (Cherry Dec. ¶¶ 10, 11.)

C. The Instant Action

On February 29, 2016, Plaintiffs filed the Consolidated Class Action Complaint in this matter. At the heart of Plaintiffs' Complaint is the repeated accusation that GNC sold supplements from third-parties containing the same two "illegal" dietary supplements as the Oregon case, picamilon and BMPEA. (Original Consolidated Complaint, e.g., ¶ ¶2-3.)

The Parties stipulated that GNC's Motion to Dismiss would be due April 12, 2016, and that Plaintiffs would have until April 26, 2016, to file an Amended Consolidated Class Action Complaint or until May 10, 2016, to file a response/opposition to the Motion to Dismiss. (Doc. No. 33.)

On April 26, 2016, Plaintiffs chose to file an Amended Consolidated Class Action Complaint, rather than oppose GNC's Motion to Dismiss. (Doc. No. 39.)

Plaintiffs' Amended Consolidated Complaint ("Amended Complaint" or "FAC") is nearly identical to the Original Consolidated Complaint except for adding allegations regarding *Acacia rigidula*, adding a plaintiff (Nate Picone) and deleting a cause of action for Breach of Implied Warranty under California's Song Beverly Consumer Warranty Act. Plaintiffs failed to remedy any of the defects pointed out in GNC's previous motion to dismiss, as such defects

cannot be remedied. Plaintiffs' Amended Complaint is fatally flawed and cannot be cured. Plaintiffs have already been provided the opportunity to cure the defects in the complaint, and failed to do so. Thus, any future request by Plaintiffs for leave to further amend should be denied. *See Vasquez v. L.A. Cnty*., 487 F.3d 1246, 1258 (9th Cir. 2007) ("Granting Vasquez leave to amend would have been futile, and we hold that the district court did not err in preventing such futility.").

i. Picamilon

Plaintiffs allege that picamilon does not qualify as a dietary ingredient under the FDCA and that it is not a lawful dietary ingredient. (FAC ¶ 43.) In support of this legal conclusion, they rely exclusively on the allegations in the OAG Action for support, citing to four pieces of "evidence": (1) the September 28, 2015, Welch Declaration discussed in detail above; (2) Russian literature; (3) the Investigative Demand to GNC made by the OAG; and (4) and a study regarding the accuracy of supplement labeling set forth in paragraph 44 of the Complaint. This "evidence" is apropos of nothing for the simple reason that the FDA has taken no enforcement action regarding picamilon and there has been no final agency action as to picamilon's lawfulness.

The OAG's own actions are illuminating. To wit, Plaintiffs and the OAG argue that picamilon was known as early as 2007 to not be a lawful dietary ingredient, yet they cannot point to anything in the public domain or any FDA agency action in support of this statement. Instead, they are forced to rely upon a declaration solicited by the OAG. In essence what plaintiffs argue is that the FDA can declare an ingredient unlawful by generating a form letter warning letter or simply reducing the opinion of an FDA official to a sworn writing. Surely, common sense and due process demands more than such regulation by fiat!

ii. BMPEA

Plaintiffs allege that GNC sold third-party products that contained BMPEA, including products containing an ingredient labeled as *Acacia rigidula* when in fact the product was actually spiked with BMPEA. In paragraphs 47-63 of Plaintiffs' Complaint, Plaintiffs refer to a myriad of sources that discuss and reference BMPEA and *Acacia ridigula*. Plaintiffs refer to, *inter alia*, a 2013 FDA study, comments by trade associations, newspaper and trade paper articles, internal GNC emails, actions by foreign regulatory agencies recalling products containing BMPEA, and a 2015 study by, among others, Dr. Pieter A. Cohen, a noted Harvard professor and frequent commentator on the dietary supplement industry. Conspicuously absent in the Complaint is any reference whatsoever to an enforcement action or final action by the FDA relating to BMPEA or *Acacia rigidula*. The reason, of course, is there were none.

In fact, Dr. Cohen's 2015 study, which is referenced in the Complaint,[8] specifically states that "[m]ore than two years after the FDA's discovery [of BMPEA in *Acacia rigidula* products], the FDA has yet to warn consumers about the presence of [BMPEA] in supplements." (Cherry Dec. Ex. A.) Dr. Cohen confirmed in the study that "FDA has been silent" regarding the consumption of *Acacia rigidula* products. (*Id.* at p. 4.) Following the release of the Cohen study, many other articles were written referring to FDA's inaction on BMPEA. Strikingly, the FDA responded through a spokesperson by saying "its review of the available information on BMPEA does not identify a specific safety concern at this time." (*Id*. at Ex. B.) Despite FDA's announced public position during the first week of April 2015, GNC began removing BMPEA products from its shelves because of the Cohen study and the stream of unfavorable articles that

[8] Documents mentioned or incorporated by reference in the Complaint can be referred to in a motion to dismiss. *See, e.g., 2 Moore's Federal Practice* § 12.34[2] (3d ed.) (courts may consider "undisputed documents alleged or referenced in the complaint" in deciding a motion to dismiss); *In re Rockefeller Ctr. Props., Inc. Sec. Litig*., 184 F.3d 280, 287 (3d Cir. 1999); *Curran v. Cousins*, 509 F.3d 36, 44 (1st Cir. 2007); *see also Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

followed. (*Id*.) FDA waited until April 22, 2015, before it reversed its position and issued warning notices to five manufacturers of products containing BMPEA. (*Id*. ¶ 5.) GNC *never* received a notice of any kind from FDA regarding BMPEA but had already begun removing BMPEA products from its shelves a full 12 days before the April 22, 2015, FDA warning letters were issued. (*Id.* ¶¶ 3-6.) Plaintiffs admit that GNC voluntarily stopped selling products identified as containing BMPEA immediately after the April 22, 2015 warning letters were issued.

iii. *Acacia rigidula*

Plaintiffs' allegations regarding *Acacia rigidula* follow the same precarious path as their allegations regarding picamilon and BMPEA. Like with picamilon and BMPEA, there has been no final agency action concerning *Acacia rigidula* and, in fact, GNC had removed products containing *Acacia rigidula* from its shelves long before the FDA issued its warning letters.

On or about April 25, 2015, GNC began pulling all products containing *Acacia rigidula* from its shelves. (Cherry Decl. ¶ 12.) This was almost a year before the FDA issued its March 7, 2016 warning letters to six other entities (not GNC) regarding *Acacia rigidula*. (FAC ¶ 67; Cherry Decl. Ex. H.)

IV. PLAINTIFFS' CLAIMS SHOULD BE DISMISSED

A. Plaintiffs Lack Standing to Pursue Their Claims.

Standing is a threshold jurisdictional requirement derived from Article III's case-or-controversy requirement. U.S. Const. art. III, § 2, cl. 1. To satisfy "the irreducible constitutional minimum of standing," the plaintiff bears the burden of establishing three elements:

> First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly ... trace[able] to the challenged action of the defendant, and not ... the result

> [of] the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992) (internal citations omitted). Although all three elements must be met, "the injury-in-fact element is often determinative." *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 138 (3d Cir. 2009).

Here, Plaintiffs have not sufficiently pled an injury-in-fact. The essence of the allegations set forth in the complaint relate to the presence of picamilon and/or BMPEA and/or *Acacia rigidula* in products. Plaintiffs allege that picamilon was not a lawful dietary ingredient and that GNC failed to inform consumers that "picamilon is a dangerous, synthetic stimulant." (FAC ¶ 47.) Plaintiffs allege that by selling picamilon and BMPEA, GNC endangered the health of its consumers. (FAC ¶ 98.) Regarding BMPEA, Plaintiffs also allege that it is not a lawful dietary ingredient and suggests that literature has suggested that it has been linked to hemorrhagic stroke in other cases. (FAC ¶¶ 61-62.) Similarly, Plaintiffs allege that *Acacia rigidula* was not a lawful dietary ingredient as it allegedly was not lawfully marketed as a dietary ingredient prior to October 15, 1994, and therefor needed premarket notification showing a history of its safe use. (FAC ¶ 70.) However, Plaintiffs do not allege that they themselves suffered any adverse health consequences as a result of consuming the products. Indeed, they do not even allege that they ever actually consumed picamilon or BMPEA or *Acacia rigidula*, merely averring that it was "purchased." (FAC ¶¶ 11-21.) For purposes of the standing inquiry, however, apprehension about a possible future injury is insufficient to establish injury-in-fact. *See, e.g., Lujan*, 504 U.S. at 560–61 (an injury-in-fact must be "(a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical"). In fact, GNC pointed this failure

out in its motion to dismiss the original consolidated complaint, but Plaintiffs failed to cure this fatal defect.

Moreover, not a single Plaintiff is alleged to have purchased the products after the date the FDA issued its warning letters on the ingredients. Thus, at the time of the purchases complained of in the Complaint, the FDA had not acted in any way to even question the use of the ingredients. In the case of picamilon, GNC vendor QNT, International, Inc. was provided with a Certificate of Free basically their products with picamilon was freely (and lawfully) marketed. GNC intends to prove in the Oregon Action that the ingredients were lawfully offered for sale. Plaintiffs lack standing for this reason, as well.

Finally, as set forth herein, Plaintiff's allegations that picamilon, BMPEA and *Acacia rigidula* are/were unlawful are belied by the facts: there has never been any final agency action declaring these ingredients to be unlawful. Simply stated, Plaintiffs lack standing to pursue this action and their action can be dismissed on this basis for lack of subject matter jurisdiction. *See Ballentine*, 486 F.3d at 810.

B. Plaintiffs' Claims Are Preempted.

i. Plaintiffs Have No Viable State Law Claims Because They Are All Predicated on Violation of the FDCA.

Plaintiffs have also failed to state a claim under Federal Rule of Civil Procedure 12(b)(6) because their claims are preempted. The Complaint should be dismissed on this ground, as well.

As a general matter, the FDCA prohibits the "introduction or delivery for introduction into interstate commerce any food . . . that is adulterated." 21 U.S.C. § 331(a). The FDCA's primary focus is ensuring that drugs are "safe, effective and not misbranded," which the FDA ensures by enforcing the regulations. *Sandoz Pharm. Corp. v. Richardson–Vicks, Inc.*, 902 F.2d 222, 230 (2d Cir.1990). The statute requires the United States (e.g., the FDA) to enforce its

provisions through injunctions, fines or imprisonment, or seizure of the adulterated food. 21 U.S.C. §§ 332-334. It is black letter law that no private individual may bring an action to enforce the FDCA**.** 21 U.S.C. § 337(a). The FDCA's text and the FDCA's legislative history make clear that Congress intended the government, not private parties, to have exclusive responsibility for enforcing the provisions of the FDCA.

Not only are direct claims under the FDCA outlawed, courts have also resoundingly rejected plaintiffs' push to invent an implied right of action for private parties to directly enforce the FDCA. Multiple lower courts have uniformly held that "Congress did not intend, either expressly *or by implication,* to create a private cause of action under the FDCA." *Bailey v. Johnson,* 48 F.3d 965, 968 (6th Cir. 1995) (emphasis added).

Over the years, plaintiffs have tried a variety of tactics to evade the federal government's exclusive enforcement authority under Section 337 of the FDCA. Some plaintiffs, like those here, tried to bury their FDCA claims in state-law causes of action. Courts have distinguished viable claims and preempted claims in the following manner:

> The plaintiff must be suing for conduct that violates the FDCA . . . but the plaintiff must not be suing <u>because</u> the conduct violates the FDCA (such claim would be impliedly preempted under *Buckman [Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 641 (2001)]). For a state law claim to survive, then, the claim must be premised on conduct that <u>both (1) violates the FDCA and (2) would give rise to a recovery under the state law even in the absence of the FDCA.</u>

Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (emphasis added); *see In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Prac. Litigation*, 701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010). "In other words, a state law claim only endures if it manages to incorporate, but not depend entirely upon, an FDCA violation and is premised on conduct that

would give rise to liability under traditional common law principles." *In re Bayer Corp.*, 701 F. Supp. 2d at 369.

Plaintiffs' Complaint contains references to the alleged unlawfulness of picamilon, BMPEA, and *Acacia rigidula* in virtually every cause of action. This mirrors the OAG Action, in which 14 out of the 17 counts in the Complaint contain references to "unlawful dietary ingredient," "lawful dietary supplement," "lawful dietary ingredient," or "lawful dietary products." Specifically, the state unfair trade practices claims here rely on the proposition that picamilon, BMPEA, and *Acacia rigidula* are not lawful dietary ingredients or dietary supplements. Significantly, Plaintiffs' rely on the federal definitions to establish the "unlawful" element of their state claims even supporting that proposition by pointing to 21 U.S.C. § 321(ff) and other relevant provisions of the FDCA.

The nature of Plaintiff's allegations demonstrate that Plaintiffs' claims fail the basic *Riley* test for preemption because the claims would not give rise to recovery in the absence of the FDCA. Plaintiffs' allegations depend entirely upon a conclusion that has not yet been reached: namely that picamilon, BMPEA, and *Acacia rigidula* have been deemed unlawful pursuant to the FDCA (a determination that may be made only by the FDA under its rule-making powers or through an enforcement action in district court). *See* 21 U.S.C. §§ 332-334. Because the ingredients have not been deemed unlawful, by FDA there can be no state law claims because no standard has been violated. The question of whether a "dietary supplement" is "lawful" exists solely because of the federal FDCA, and in the absence of the FDCA, no allegedly wrongful conduct remains. Because picamilon, BMPEA, and *Acacia rigidula* have never been declared to be unlawful dietary ingredients, the entirety of Plaintiffs' case collapses.[9]

[9] Even if the court considers the pronouncements in the warning letters that the ingredients are not lawful dietary ingredients, GNC had already pulled the products as of the dates of the letters.

ii. Claims Relating to BMPEA "spiking" are Also Preempted

Certain of Plaintiffs' claims are preempted for another reason. Plaintiffs allege that certain products listed the ingredient *Acacia rigidula* when they were actually "spiked" with BMPEA, failing to identify BMPEA as an ingredient. Claims regarding the nutrient content of products sold by GNC are preempted.

21 C.F.R. § 101.9(g)(2) requires that the "sample for nutrient analysis shall consist of a composite of 12 subsamples consumer unites, taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot." The methodology described in section 101.9(g)(2), commonly known as the "12-sample methodology", is required to be used to determine "compliance with the requirements for nutrient content claims." *See* 21 C.F.R. § 101.13(o) ("Except as provided in § 101.10, compliance with requirements for nutrient content claims in this section and in the regulations in subpart D of this part, will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9.") Section 101.36 addresses nutrition labeling of dietary supplements, and requires compliance with Section 101.9(g)(1) through (g)(8).

District courts have found that because the FDA regulations provide that the question of compliance must be determined using the method specified by section 101.9 of the regulations, a state law claim that seeks to establish a violation of such regulation by a methodology different than the 12-sample methodology is preempted. *See Burke v. Weight Watchers Int'l, Inc.*, 983 F.Supp.2d 478, 480, 483 (D.N.J. 2013); *Salazar v. Honest Tea, Inc.,* 74 F.Supp.3d 1304, 1313 (E.D. Cal. 2014); *Mee v. I A Nutrition, Inc.*, No. C-14-5006 MMC, 2015 U.S. Dist. LEXIS 63038, 2015 WL 3351303, at 4 (N.D. Cal. May 13, 2015); *Vital v. One World Co., LLC,* No. SACV 12-00314-CJC (MLGx), 2012 U.S. Dist. LEXIS, 186203, at *2, *13-18 (C.D. Cal. Nov. 30, 2013.)

Nowhere in Plaintiffs' Complaint do they allege that a 12-sample methodology was used to show that these products did or did not contain BMPEA in addition to *Acacia rigidula*. Rather, Plaintiffs alleged analysis using LC/MS and GC/MS. (FAC ¶ 50.) The reason that for failing to allege the 12-sample methodology is clear: it was not done and there is simply no way for Plaintiffs to amend around this fact. Because Plaintiffs fail to allege sufficient facts that the nutrient claims regarding the presence or absence of BMPEA were violated under the 12-sample methodology these claims are also preempted.

C. There Has Been No FDA Enforcement or Final Agency Action as to Picamilon, BMPEA or *Acacia rigidula*.

For Plaintiffs' claims to survive this motion, they must demonstrate the impossible, namely that there has been final agency action against GNC as to both picamilon, BMPEA, and *Acacia rigidula*. Plaintiffs cannot even show the initiation of an enforcement action against GNC, or anyone else, let alone a final agency action.[10]

As a general matter, two conditions must be satisfied for an agency action to be "final." First, the action must mark the consummation of the agency's decision making process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal citations and quotation marks omitted); see A*T & T Co. v. EEOC*, 270 F.3d 973, 975 (D.C.Cir.2001). As is set forth below, declarations and warning letters do not constitute enforcement actions and cannot be deemed final agency actions.

[10] That fact is evident by simple comparison of the form letter warning that FDA sends out that simply threatens the possibility of enforcement action if products are involuntary removed from the market.

i. The Welch Declaration Does Not Constitute an Enforcement Action or Final Agency Action.

Nowhere in the FDCA is there any provision stating that an enforcement action can be initiated by way of a declaration of an FDA official. To find that such any declaration constitutes a FDA enforcement action would be unprecedented. *See Biotics Research Corporation v. Heckler*, 710 F.2d 1375 (1983) (holding that regulatory letters issued by the FDA did not constitute a final decision by the FDA and that letters did not commit the FDA to enforcement action.) To be clear, the Welch Declaration is nothing more than Dr. Welch's view. [11]

Moreover, such a declaration fails to meet the requirements of final action under the Administrative Procedures Act ("APA"), as it does not appear to mark the culmination of any decision-making process and rights or obligations are not determined. *See* 5 U.S.C. § 704. Additionally, it cannot be said to be something from which legal consequences will flow because it was never even provided to GNC by the FDA. Put simply, the Welch's Declaration cannot be deemed an enforcement action or final agency action—a fact that Plaintiffs acknowledge by failing to allege that the Welch Declaration rises to such a level. In reality, the only actual use of the Welch Declaration has been as an exhibit in support of the OAG action!

ii. Warning Letters Are Not Enforcement Actions or Final Agency Actions.

Most courts to consider the question have held that an FDA warning letter does not constitute a final agency action. *Cody Labs., Inc. v. Sebelius*, 446 Fed. App'x 964, 969 (10th Cir.

[11] 21 CFR 10.85(k): "A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."

2011). Instead, FDA warning letters are considered informal and advisory. *See*, FDA Regulatory Practices Manual—July 2012; 4-1-1.[12] Indeed, warning letters are not even the initiation of an enforcement action. *Holistic Candlers and Consumer Ass'n v. U.S. Food and Drug Admin.*, 770 F.Supp.2d 156, 160-161(D.D.C. 2011), *aff'd sub nom. Holistic Candlers and* Consumers *Ass'n v. Food & Drug Admin.* (D.C. Cir. 2012) 664 F.3d 940. Although GNC took swift action to remove all products at issue referenced in the FDA's warning letters, the fact remains that the FDA has never pronounced either ingredient to be unlawful.

Indeed, warning letters simply communicate the agency's position on a matter without committing the FDA to an enforcement action. *See*, FDA Regulatory Practices Manual—July 2012; 4-1-1. (See Request for Judicial Notice and Declaration of Amy B. Alderfer, Ex. L.) A Warning Letter typically results in a process of discussion, negotiation, and analysis involving the FDA and interested parties. Following this process, the FDA may choose to modify or rescind a Warning Letter altogether.

For that reason, even the FDA itself does not consider a warning letter a final action on which it can be sued. *Holistic Candlers and Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 944-45 (D.C. Cir. 2012). After issuing a Warning Letter, the FDA may choose to initiate enforcement proceedings, which may result in a final agency action and resulting appeal. Unless and until that occurs, however, there has been no binding resolution of the issues raised in the Warning Letter.

Regarding picamilon, GNC never received any of the warning letters sent out by the FDA on or about November 30, 2015 from FDA itself. (Cherry Dec. ¶ 11.) The letters specifically warn recipients that the "failure to immediately cease distribution of the offending product could

[12] http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf (Alderfer Dec., Ex. L.)

result in enforcement action by FDA without further notice." (*Id*. Ex. G.) This was the first notification that GNC received (indirectly) from FDA concerning picamilon. Notably, even if these warning letters had been sent directly to GNC from the FDA, under current law, the letters did not initiate an enforcement action, did not commit the FDA to an enforcement action, and did not constitute final action. Rather, the warning letters were informal and advisory.

The same is true of the April 22, 2015 warning letter received regarding BMPEA. (Cherry Dec. ¶¶ 5-6.) Again, this was the first public communication from FDA regarding products containing BMPEA (and again was not sent directly to GNC by the FDA), but this warning letter does not constitute an enforcement action or a final action by FDA and it confers no right of enforcement on Plaintiffs.

Regarding *Acacia rigidula*, as admitted by Plaintiffs, warning letters were not sent until March 7, 2016. (FAC ¶ 67.) What Plaintiffs fail to tell this Court is that warning letters regarding *Acacia rigidula* were not even sent directly to GNC by the FDA. (Cherry Decl. ¶ 14.) These letters were however the first public communications from FDA regarding products containing *Acacia rigidula*. Just as with picamilon and BMPEA, a warning letter does not constitute an enforcement action or a final action by FDA and it confers no right of enforcement on Plaintiffs.

To this date, questions regarding the legality of BMPEA, picamilon, and *Acacia rigidula* are far from settled. The Warning Letters are simply preliminary statements of the agency's position, which may be modified or rescinded by the agency or rejected in a subsequent enforcement action or appeal. Accordingly, although the FDA may have issued Warning Letters for some products containing BMPEA, picamilon, and *Acacia rigidula*, it does not follow that the issue of the lawfulness of these ingredients is now undisputed. These letters are one step in a

process, but not a final determination. What's more, even ignoring the above legal truisms, GNC had begun removing (1) BMPEA products 12 days before the FDA BMPEA warning letters were sent to others, (2) over 60 days before the FDA picamilon warning letters were sent to others; (3) almost a year before the FDA *Acacia rigidula* warning letters were sent to others.

iii. Allowing Declarations and Warning Letters to Serve as Final Agency Action for Purposes of this Litigation Would Deprive GNC of Its Due Process Rights.

Under the APA there is a judicial right of review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704; *see Trudeau v. Federal Trade Com'n*, 456 F.3d 178, 185 (D.C. Cir. 2006) ("'If there was no final agency action ..., there is no doubt that appellant would lack a cause of action under the APA.'" (quoting *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 731 (D.C.Cir.2003))). As noted in *Holistic Candlers and Consumers Ass'n v. Food & Drug Admin.* 664 F.3d 940, 943 (D.C. Cir. 2012), the "FDA's warning letters fail to satisfy either condition: they neither mark the consummation of the agency's decision making process nor determine the appellants' legal rights or obligations."

Here, Plaintiffs are seeking to hold up as "final" action form warning letters and a declaration, things which do not even initiate an action let alone indicate final agency action. Moreover, GNC had no legal opportunity to challenge the warning letters and the declaration as they would not have been considered "final action" subject to judicial review. To be sure, had GNC attempted to challenge either the declaration or the warning letters it would have been found to have no cause of action under the APA as FDA would have argued that these were not final actions. Thus, allowing a declaration and warning letters to serve as final actions for purpose of this litigation would rob GNC of its due process rights, as GNC would be bound by a declaration and warning letters that it had no ability to challenge in a judicial action because they

did not constitute final action under the APA. Moreover, how is GNC supposed to have notice of the actions of certain FDA officials, which do not amount to agency action or FDA enforcement actions, remains a mystery. Forcing GNC to respond to subrosa FDA "action" is tantamount to being put on "double secret probation." Finally, it is axiomatic that if BMPEA, picamilon, and *Acacia rigidula* were not unlawful under the FDCA, the mislabeling and adulteration claims here would not lie.

D. Plaintiffs' Claims Should Be Dismissed Because of the FDA Guarantee.

The FDCA provides penalties for persons who violate certain provisions of the Act. However, Section 303, paragraph (c) of the Act states that no person shall be subject to the penalties of subsection (a)(1) for having received, or proffered delivery of, adulterated or misbranded food additives if he has established a good faith guarantee from whom he received the articles. This paragraph was included in the 1958 amendments to the Federal Food, Drug and Cosmetic Act and remains the legal basis for the "letter of guaranty" supplied by many manufacturers to their clients.[13]

Here, GNC did not manufacture or sell under the GNC brand any products containing BMPEA, picamilon, and *Acacia rigidula*. (Cherry Dec. ¶ 2.) Moreover, GNC can establish that its third-party vendor agreements provide that the vendors warranted that the goods were manufactured, packaged, stored and shipped in accordance with the applicable standards of Good Manufacturing Practices promulgated under the FDCA and all applicable federal, state, and local laws, rules and regulations. GNC is entitled to rely on its vendors pursuant to the plain terms of the FDCA. The FDA Guarantee provides GNC with immunity from misdemeanor prosecution under the FDC Act, limiting even FDA's ability to prosecute violations where intent is absent,

[13] *See* http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/ucm095327.htm (Alderfer Dec., Ex. M.)

and establishing that Congress did not intend that retailers who rely in good faith on the guarantees of third party vendors be held accountable for the actions of those vendors, except in unusual circumstances not present here. Accordingly, plaintiffs cannot state a claim for relief.

V. CONCLUSION

For the reasons set forth above, GNC respectfully requests that this Court grant its Motion to Dismiss Plaintiffs' First Amended Consolidated Complaint in its entirety.

Dated: May 26, 2016

/s/ Amy B. Alderfer

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